



# PRECTAVI®

PREDICTIVE PROCESS  
CONTROL

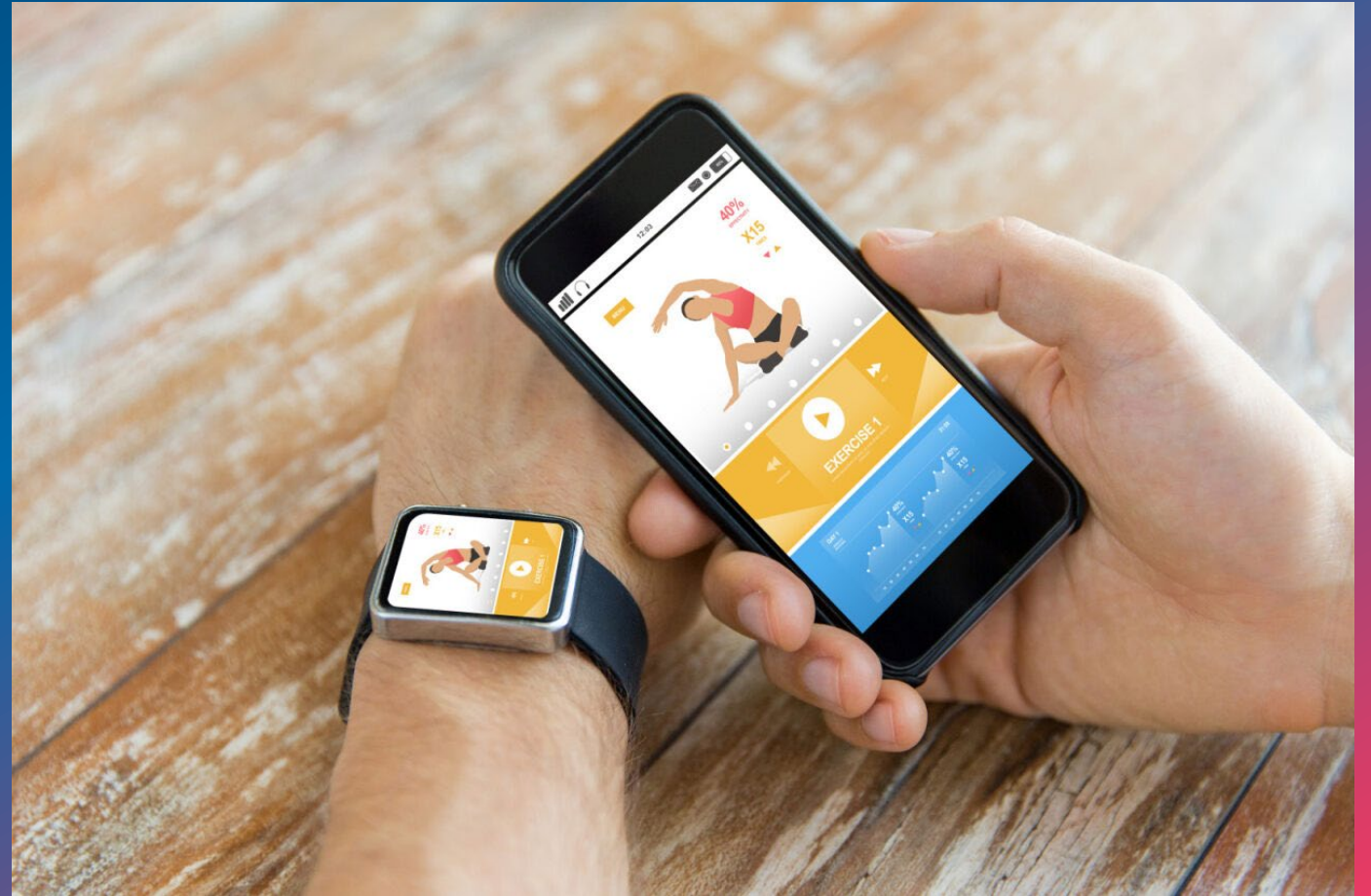
**Dr. Peter Heym**  
Strategic Advisor



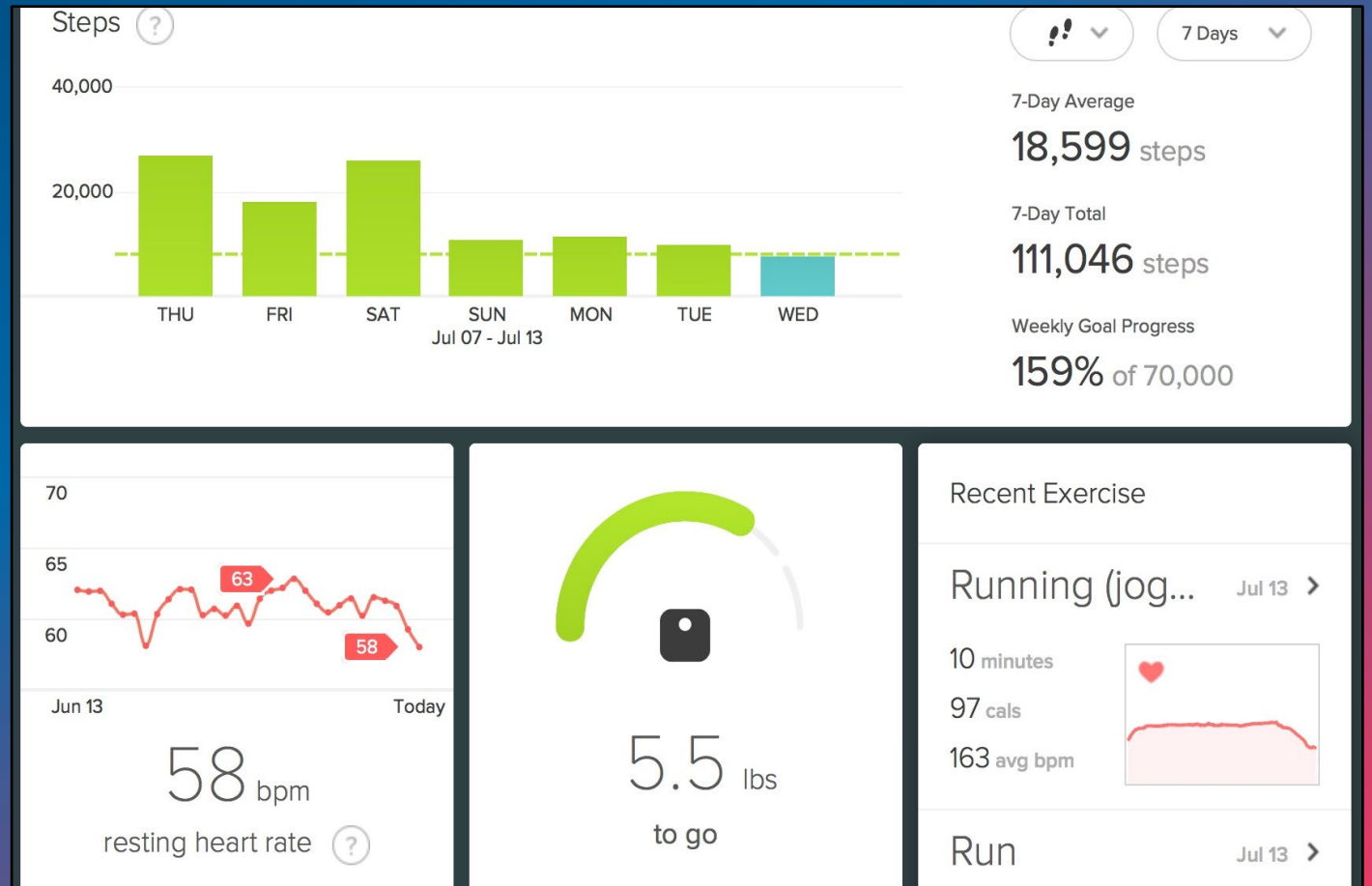
**Michael Gerber**  
Manager Business Development



Who tracks his / her fitness and health data?



...and who is using the gained data to improve their habits?



## Pharmaceutical industry might be behind the curve in terms of full utilization of the available data



Huge amount of present data remain unexploited



Majority of manufacturing data exist in analog form

## This creates issues and opportunities at the same time



### Increased quality costs

- Batch failures and reworks
- Product recalls
- Downtimes
- Administrative &  
Investigative costs



### Unrealized operational efficiency gains

- OEE improvements
- Optimization of resources
- Lead time reduction

...and at the same time

Increasing  
competitiveness  
in markets &  
rising number of  
highly complex  
products

Authorities  
increasingly  
tighten up  
requirements  
around QA via  
formal statistical  
review, i.e. CPV

Pharmaceutical  
companies  
create acute  
awareness on  
this situation with  
industrial  
stakeholders

With state-of-the-art AI-driven tools, PRECTAVI offers a solution for both manufacturing and QA challenges and opportunities



**Data collection**



**Reporting advice**



**Data cleaning / processing**



**Historic and predictive analysis**

- pro-active and real-time monitoring
- critical process parameters
- uni- and multi-variate analyses

# How AI enhances digital transformation in pharmaceutical manufacturing with PRECTAVI



## Data Collection

- Digitalization of paper-based data
- Document recognition with 99% accuracy
- multiple sources data aggregation (e.g., LIMS, MES and sensor data)

1



## Data Processing

- Automated error and inconsistency detection
- Automated data cleaning
- Automated data transformation

2



## Data Transformation

- Univariate analysis incl. statistical control charts with numerous analytical features
- AI-supported multivariate analysis to detect batches of interest.
- AI supported real-time analysis

3



## Reporting

- QA and production reporting for CPV/PQR or customized KPIs
- Automated generation of printable report documents with customizable elements
- Planned: Fully automated text generation via Generative AI

4



## Advice

- Automated root cause analysis
- Suggestion of corrective actions
- Process improvement and re-evaluation advice

5



# Solution Landscape



File Upload

User



Sensor Data



Product Quality

LIMS



Process Data

SAP, MES



User



3rd party Management

# Solution Landscape



User

File Upload



File Upload and digital service



Post-Production Analytics Services



Reporting Services



Document & Data Services



Data Processing Services



Sensor Data



Sensor Data & Rest API



Batch Real-Time Analytics



Advice Services



Product Quality



Integration Services



Batch & Batch Series Management

LIMS



Process Data



User Administration



Data Export Services



User



3rd party Management

SAP, MES

● Base Modules (in Scope)

● Extension - customized

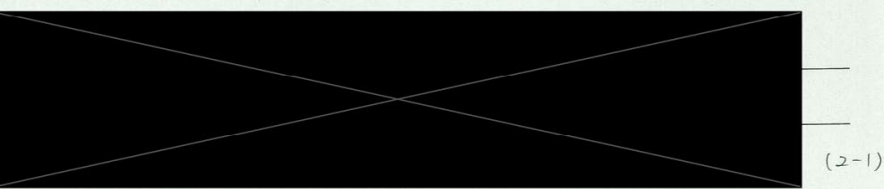


# PRECTAVI data collection & processing

**CERTIFICATE OF ANALYSIS**

Product : [REDACTED]  
 Lot Number : 20201YU  
 Date of Manufacture : 15/Sep/2020  
 Packaging Date : 03/Dec/2020  
 Intermediate Lot : YU20001  
 Quantity : 28213 vials  
 Expiry Date : 31/Aug/2023  
 Cap color : Pink  
 Outer cap diameter : 17.8±0.3 mm  
 Manufacturer : [REDACTED]

Test Items	Acceptance criteria	Results
Appearance (USP/EP)(Color)	Color : ≤ BY <sub>s</sub>	≤ RY <sub>7</sub>
Appearance (USP/EP)(Clarity)	Clarity : ≤ II	≤ I
Appearance (JP)	Colorless Clear solution	Colorless Clear solution
Appearance (Visible particles)	Without visible particulates	Without visible particulates
Appearance (Visible particulates)	Essentially free from visible particulates	Essentially free from visible particulates
Appearance (Foreign insoluble matters)	Free from readily detectable foreign insoluble matters	Free from readily detectable foreign insoluble matters
pH(JP/USP)	6.00 - 6.50	6.32
pH(EP)	6.00 - 6.50	6.28
Osmolality (USP/EP)	257 - 315 mOsmol/kg	284 mOsmol/kg
Osmolality (JP)	0.9 - 1.1	1.0
Particulate matter in injections (USP/EP)	≥ 10 µm : ≤ 6000 particles/vial	7 particles/vial
Particulate matter in injections (USP/EP)	≥ 25 µm : ≤ 600 particles/vial	0 particles/vial
Particulate matter in injections (JP)	≥ 10 µm : ≤ 6000 particles/vial	7 particles/vial
Particulate matter in injections (JP)	≥ 25 µm : ≤ 600 particles/vial	0 particles/vial
Volume in container	Minimum Volume ≥ 1.0 mL	1.0 mL
Volume in container	Maximum Volume ≤ 1.3 mL	1.2 mL
Polysorbate 80	0.40 - 0.60 mg/mL	0.50 mg/mL
Methionine	8.0 - 12.0 mmol/L	9.8 mmol/L
Protein concentration	18.0 - 22.0 mg/mL	20.2 mg/mL
Identity : Antigen-binding ELISA	Positive identity	Positive identity
Purity : SE-HPLC	Main peak : ≥ 98.0 %	98.6 %
Purity : SE-HPLC	HMWS : ≤ 1.2 %	0.8 %
Purity : CE-SDS (R)	Main peaks (HC+LC) : ≥ 96.4 %	97.5 %
Purity : CE-SDS (R)	LMWS : ≤ 0.5 %	0.2 %
Purity : CE-SDS (R)	MMWS : ≤ 0.6 %	0.3 %
Purity : CE-SDS (R)	DSHC : ≤ 1.3 %	0.7 %
Purity : CE-SDS (NR)	Main peak : ≥ 96.5 %	97.5 %
Purity : CE-SDS (NR)	LMWS : ≤ 3.3 %	2.4 %
Purity : CEX-HPLC	Acidic peaks : 19 - 32 %	26 %
Purity : CEX-HPLC	Main peak : 43 - 54 %	49 %
Purity : CEX-HPLC	Basic peaks : 15 - 36 %	26 %
Potency : Egr-1 reporter gene assay	89 - 111 %	98 %
Contaminants : Bacterial endotoxins	≤ 2.0 EU/mL	< 0.18 EU/mL
Contaminants : Sterility	Sterile	Sterile



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PETER HEYM  
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- Portal
- Batch Series
- Reporting
- Settings

Logout


Batch Series **DiamondCure**

Product Type : [REDACTED] Dosage Form : [REDACTED]  
 Input Material : [REDACTED]  
 Product Number/Code : [REDACTED] Manufacturer/Supplier : [REDACTED]  
**DiamondCure** **DiamondCure**

Original Processed **Both**

Feature	Limits
Acceptance Criteria/Limit	
Free from readily detectable foreign i...	
<b>pH(JP/USP)</b> 6.00 - 6.50	≥ 6 ≤ 6.5
<b>pH(EP)</b> 6.00 - 6.50	≥ 6 ≤ 6.5
<b>Osmolality (USP/EP)</b> 257 - 315 mOsmol/kg	≥ 257 ≤ 315
<b>Osmolality (JP)</b> 0.9 - 1.1	≥ 0.9 ≤ 1.1
<b>Particulate matter in injections (USP...)</b> ≥ 10 µm : ≤ 6000 particles/vial	≥ 10 ≤ 6000
<b>Particulate matter in injections (USP...)</b> ≥ 25 µm : ≤ 600 particles/vial	≥ 25 ≤ 600
<b>Particulate matter in injections (JP)</b> ≥ 10 µm : ≤ 6000 particles/vial	≥ 10 ≤ 6000
<b>Particulate matter in injections (JP)</b> ≥ 25 µm : ≤ 600 particles/vial	≥ 25 ≤ 600

# PRECTAVI Feature Details



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Portal

Batch Series

Reporting

Settings

**Batch Series** DiamondCure
^

Data
Analysis

Product Type  
**Input Material**

Product Number/Code  
**DiamondCure**

Dosage Form

Manufacturer/Supplier  
**MagicCured GmbH**

Strength

Series Status

Date First Batch - Last Batch  
-

Batch Count  
**90**

Feature Overview
Feature Detail
Feature Correlation

**Polysorbate 80**

**Data**

Sequenz ID	Batch	Batch Date	Value
18	CoA_27.pdf		1.98
19	CoA_28.pdf		1.96
20	CoA_29.pdf		1.64
21	CoA_30.pdf		1.8
22	CoA_31.pdf		1.82
23	CoA_32.pdf		1.78
24	CoA_33.pdf		1.65
25	CoA_34.pdf		1.63

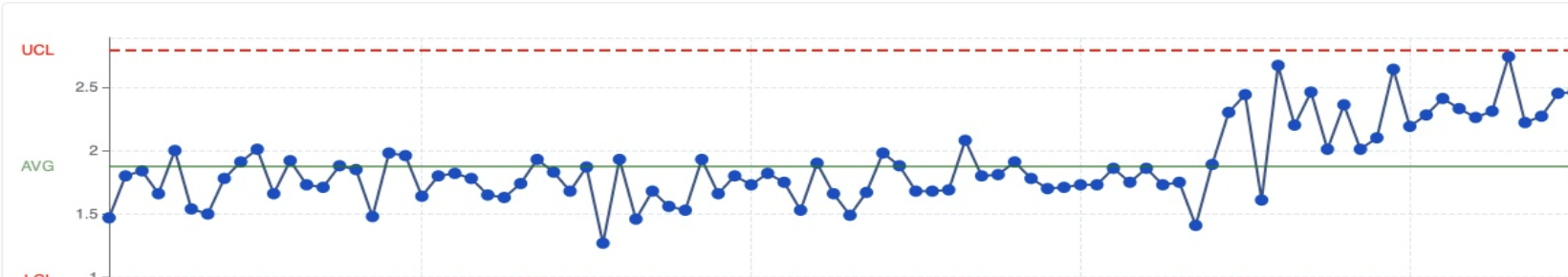
**Descriptive Statistics**

Metric	Value
Count	90
Mean	1.88
Std	0.30
Min	1.27
Max	2.74
25%	1.68
50%	1.81
75%	2.01

**Process Capability and Performance**

Metric	Value
Shaporio-Wilks	0.94
SW-Probability	0.00
Kolmogorov-Smirn...	0.91
KS-Probability	0.00
Pp	1.00
Ppk	1.00
Cp	n/a
Cpk	n/a

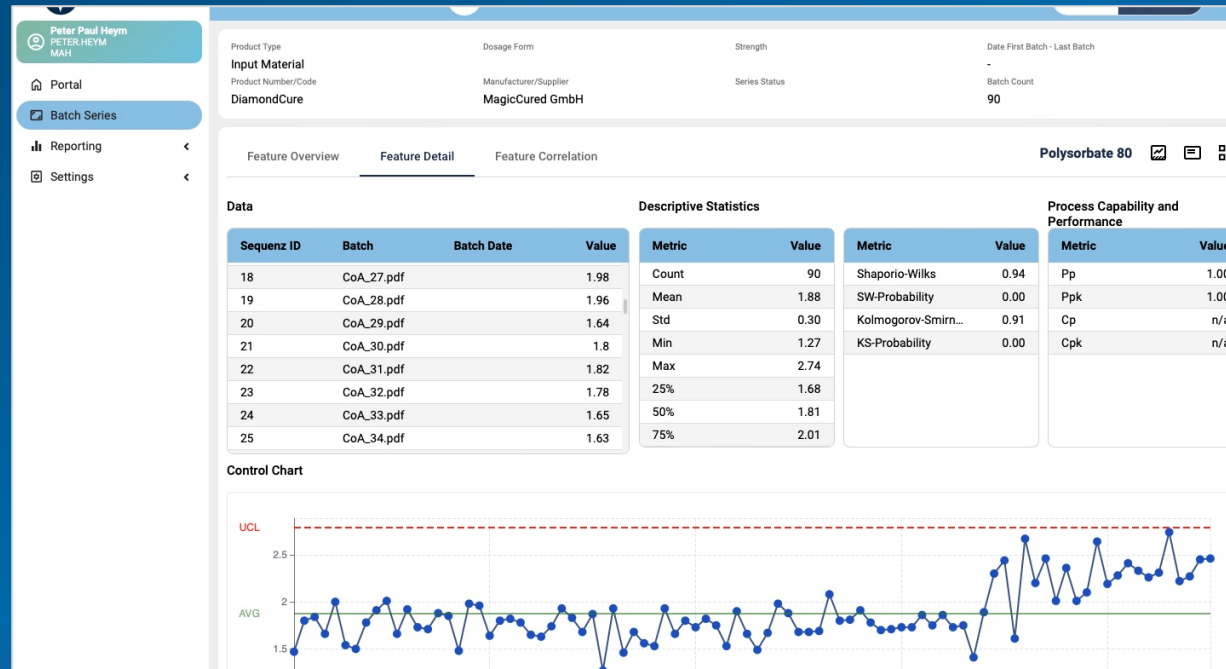
**Control Chart**



# PRECTAVI Feature Details

## First-glance analysis of single quality attribute

- Intuitive investigation of individual batch data or multiple batch series
- Univariate analysis, summary statistics for general overview



## In-depth analysis of single quality attribute

- Process Capability & Performance Indices
- Classical SPC (Statistical Process Control) Charts
- Interactive Nelson Rules-based detection of trends and patterns

# PRECTAVI Feature Overview

**PRECTAVI**

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- Portal
- Batch Series**
- Reporting
- Settings

**Batch Series DiamondCure**

Data Analysis

Product Type	Dosage Form	Strength	Date First Batch - Last Batch
<b>Input Material</b>			-
Product Number/Code	Manufacturer/Supplier	Series Status	Batch Count
<b>DiamondCure</b>	<b>MagicCured GmbH</b>		<b>90</b>

Feature Overview | Feature Detail | Feature Correlation

Search

### OSMOLALITY

UL: 310  
UCL: 290  
AVG: 290  
LCL: 288  
LL: 260

### POLYSORBATE80

UCL: 2.5  
AVG: 1.8  
LCL: 1.0  
UL: 0.5  
LL: 0.5

### METHIONINE

UL: 12  
UCL: 11  
AVG: 10  
LCL: 9  
LL: 8

### PROTEINCONCENTRATION

UCL: 22  
AVG: 21  
LCL: 20  
UL: 18  
LL: 18

# PRECTAVI Feature Overview

## Intuitive multiple quality attributes analysis

- Multivariate & machine learning-assisted analysis for multiple attributes
- Allow for detection of similarities in patterns
- Suggestions for root-cause analysis



## Sharing insights – Reporting and advise

- Multivariate trend & root-cause analysis lead to:
- AI-assisted suggestions drive suggestions for continuous improvement
- Fulfilling needs from authorities



## We offer

- Software-as-a-Service Solution
- Consulting
- Setup support
- User Training
- Customization
- Regulatory Affairs Support

## Your benefits

- Scaling of Analyses
- Pro-Active and Automated Analytics
- Reduced Effort and QA costs
- Reduced time to market
- Reduced failure rates
- Improved yield





# R+regenold

- Leading regulatory affairs advisory headquartered in Germany with own staff of c170
- Focus on pharmaceutical & medical devices
- Full coverage of the product life cycle from development to market access
- International coverage through own subsidiaries (UK, IRE, CH, PRT) and proprietary network Regulanet

- International IT Specialist for Digital Transformation
- Decades of experience
- Extensive industry expertise
- Excellent technology know-how
- Strong partner network



This is what PRECTAVI can do for you.

Let us have a chat about your individual challenges and how we can support you!



Thank You for Your Attention!